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October 11, 2004

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Ref.
FDA Interim Final Rule prohibiting use of certain cattle materials that may carry the risk of Bovine Spongiform Encephalopathy in Human Foods and Cosmetics.

Dear Sir or Madam:

Pursuant to FDA's Interim Final Rule under 21 CFR Parts 189 and 700 [Docket No. 2004N-0081] Use of Materials Derived From Cattle in Human Food and Cosmetics, we would like to make the following comments:

As part of this interim final rule, prohibited cattle material includes material from non-ambulatory disabled cattle and cattle not inspected and passed for human consumption. In the preparation of certain raw materials for use in cosmetics, feed stock for certain highly processed protein derivatives may fall into the category of cattle not inspected for human consumption, but poses no risk of transfer of BSE or BSE related illness.

Risk can be considered nonexistent because the source material is originally dermal collagen from US sourced cattle - a low risk, Category IV (No Detectable Infectivity) material. It does not contain and is not derived from specific risk materials as defined in the EEC Commission Directive 97/534/EC.

These reactions involve protein hydrolysis through the use of highly alkaline and/or enzymatic processes, including sterilizing at 100°C for 8-12 hours minimum. Some products undergo post reactions with a variety of derivitizing agents such as acyl chlorides and quaternizing agents, rendering the feedstock into a new chemical entity, not the original protein.

Specifically, collagen products derived from tanned leather are digested/solubilized with large amounts of lime at 130 °C under high pressure conditions, for 3 hours. Some of these products undergo acidulation (pH 2-3) during an additional purification stage.

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Any potential causative infective agents that could even theoretically be present in these products, however inconceivably, would be rendered inactive by conversion to chemical compounds unrecognizable either chemically or biologically as coming from the original source proteins.

In common layman's terms, two primary source materials used for bovine derived cosmetic proteins are leather and gelatin. Traceability of both materials to cattle origin is not feasible under current industry practices.

Leather undergoes extreme chemical processing by a series of proprietary complexation and cross-linking steps. Leather articles are not currently suspected of infectivity regardless of the cattle source. In the case of leather based products, we would petition that products made from this feed stock, leather, be exempt from the restriction of originating from inspected, passed for human consumption, ambulatory cattle and not be classified as prohibited cattle material.

Gelatin can be both certified food grade or industrial grade. Neither are currently traced to cattle origin, but can now be differentiated into food and non-food grade. Non-food grade gelatin is not necessarily inspected for human consumption. We would petition that because of the extreme processing of cosmetic grade collagen products, that gelatin (both food and non-food grade) derived products for cosmetic use be exempt from the interim rule. Alternatively, a restriction that source gelatin be originally from food grade material for cosmetic use could be acceptable, if a reasonable grace period for compliance be allowed to give gelatin suppliers ample time to establish systems for tracing source cattle to inspected cattle for human consumption. The current situation is such that gelatin for food use itself is not traceable according to at least one major manufacturer. This interim rule does not take into consideration the cost impact or ability of gelatin producers to certify to trace cattle to their origin. Nor does it take into consideration that other cattle derived ingredients from inedible rendering (i.e. tallow-derived products) are used to a significant extent. These protein-derived ingredients represent another large portion of cosmetic ingredients.

The Harvard-Tuskegee study used to judge reduction of risk to BSE infectivity of materials does not address either the true risk of infectivity from exposure in cosmetics nor the reduction of risk associated with use of cattle only inspected for human consumption. Both of these issues, the extension of this rule to cover externally applied cosmetics and the inclusion of cattle not inspected for human consumption in the prohibited cattle materials are predicated on unfounded assumptions about potential for infectivity. The reduction of risk to BSE infectivity by these restrictions has not been demonstrated and is unfounded.

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Can you please comment on and consider these issues in revising the interim final rule on prohibited cattle materials specifically as they impact non-tallow bovine derived ingredients in cosmetics.

Thank you for your consideration.

Sincerely,

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